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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/669,187	09/25/2000	Arthur M. Krieg	C1039/7035 (HCL/MAT)	2999

7590 08/09/2006

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EXAMINER	
BLANCHARD, DAVID J	

ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 08/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/669,187	KRIEG ET AL.	
	Examiner	Art Unit	
	David J. Blanchard	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *121-138* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *121-138* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/3/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 15 June 2006 has been entered.

2. Claims 1-120 are cancelled.

3. Claims 121-138 are pending and under examination.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. This Office Action contains New Grounds of Rejections.

Information Disclosure Statement

6. The information disclosure statement (IDS) submitted on 03 July 2006 has been fully considered by the examiner. A signed copy of the IDS submitted on 03 July 2006 is included with the instant Office Action.

Objections/Rejections Withdrawn

All objections and rejections in the previous Office Action mailed 1/13/2006 are withdrawn in view of the cancellation of the claims.

New Grounds of Objections/Rejections

7. Claim 121 is objected to because of the following informalities:

Although one of skill in the art could readily determine the metes and bounds of the claim, claim 121 is objected to as being an improper Markush-type claim in the recitation "one or more of carboplatin, paclitaxel, cisplatin, 5-fluorouracil, doxorubicin and gemcitabine". Applicant is reminded that a Markush-type claim recites alternatives in a format such as "selected from the group consisting of A, B and C." See Ex parte Markush, 1925 C.D. 126 (Comm'r Pat. 1925). MPEP 803.02. Consider revising claim 121 to recite "one or more chemotherapeutic agent selected from the group consisting of carboplatin, paclitaxel, cisplatin, 5-fluorouracil, doxorubicin and gemcitabine...", provided no new matter is introduced.

Appropriate correction is required.

8. Claims 121-138 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 121-138 are indefinite in the recitation "one or more of carboplatin, paclitaxel, cisplatin, 5-fluorouracil, doxorubicin, taxol and gemcitabine..." in claim 121 because paclitaxol is also known in the art as taxol (Taxol™). Thus, it is unclear what is contemplated by the selection of paclitaxol and/or taxol (Taxol™) as the two names refer to the same molecule.

b. Claim 121 contains the trademark/trade name Taxol™. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name.

9. Claims 121-124 and 128-132 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating cancer in a subject comprising administering the unmethylated immunostimulatory oligonucleotide of SEQ ID NO:246 comprising a modified backbone and a chemotherapeutic agent, does not reasonably provide enablement for a method of treating cancer in a subject comprising administering the immunostimulatory oligonucleotide of SEQ ID NO:246 and a chemotherapeutic agent, wherein the oligonucleotide is unmethylated and lacks a phosphate backbone modification. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 1 12, first paragraph, have been described by the court in *In re Wands*, 8 USPQ2d 1400 (CA FC 1988).

Wands states on page 1404,
"Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims."

The claims are drawn to a method of treating a subject having cancer comprising administering an immunostimulatory oligonucleotide comprising SEQ ID NO:246 and one or more of carboplatin, paclitaxel (taxol), cisplatin, 5-fluorouracil, doxorubicin, and/or gemcitabine in an effective amount to treat the cancer and wherein the oligonucleotide is up to 100 nucleotides in length, is 24-40 nucleotides in length is administered by injection and wherein the subject is a human and the cancer is non-small cell lung cancer. Thus, the claims embrace administering an immunostimulatory oligonucleotide wherein the oligonucleotide is unmethylated and is not protected from nuclease degradation for the clinical use in cancer therapy.

The specification teaches that the immunostimulatory oligonucleotide consisting of SEQ ID NO:246 and having a phosphorothioate backbone is immunostimulatory (see Examples). The specification does not teach the treatment of cancer in a subject comprising administering the immunostimulatory oligonucleotide of SEQ ID NO:246 or in combination with one or more of carboplatin, paclitaxel (taxol), cisplatin, 5-fluorouracil, doxorubicin, and/or gemcitabine in an effective amount to treat the cancer. There are no working examples treating cancer in a subject comprising administering the immunostimulatory oligonucleotide of SEQ ID NO:246 and one or more of carboplatin, paclitaxel, cisplatin, 5-fluorouracil, doxorubicin, and/or gemcitabine in an

effective amount to treat the cancer. The scope of the claims must bear a reasonable correlation with the scope of enablement. See *In re Fisher*, 166 USPQ 19 24 (CCPA 1970).

The state of the prior art is such that it is well established that the immunostimulatory oligonucleotides should be unmethylated and protected from endogenous nucleases for in vivo clinical use.

For instance, Krieg (BioDrugs, 5:341-346, 1998) teaches,

"Synthetic oligonucleotides ranging in length from 8 to 30 nucleotides or more could cause immune stimulation if there was only a single CpG dinucleotide as long as this was not preceded by a C or followed by a G. Most importantly, the CpG dinucleotide had to be unmethylated: if the C was replaced by s-methyl-cytosine, then the oligonucleotide lost its immune stimulatory activity." (See p. 342, first paragraph).

Similarly, Agrawal et al. (Trends in Mol. Med, 8:114-121, 2002) teaches, "The presence of unmethylated CpG dinucleotide is essential for the induction of immunostimulatory activity..." (See pg. 114, bottom of second column). Agrawal also teaches that sequences required for CpG related immune stimulation varies from species to species, and indicates, "The optimal motif for recognition by human immune cells is GTCGTT or TTCGTT" (See pg. 115, first paragraph). Hartmann et al. (J. Immunology, 164:1617-1624, 2000) teaches that the oligonucleotide must be protected from nuclease degradation in order to be effective in vivo. Specifically, Hartmann teaches, "To have in vivo clinical utility, ODN must be administered in a form that protects them against nuclease degradation. The native phosphodiester internucleotide linkage can be modified to become highly nuclease resistant via replacement of one of the non-bridging oxygen atoms with a sulfur, which constitutes phosphorothioate ODN."

(see pg. 1618, 1st column). The specification provides no direction or guidance to assist those skilled in the art in the administration of an unmethylated or methylated immunostimulatory oligonucleotide comprising or consisting of SEQ ID NO:246 and lacking a backbone modification in combination with one or more of carboplatin, paclitaxel (taxol), cisplatin, 5-fluorouracil, doxorubicin, and/or gemcitabine for the treatment of cancer in a subject. In view of the art of Krieg, Agrawal et al and Hartmann et al, and the lack of guidance and direction in the specification, one of skill in the art could not predictably extrapolate the disclosed immunostimulatory properties of SEQ ID NO:246, which is unmethylated and comprises a phosphorothioate modification to the claimed therapeutic method in cancer subjects comprising the administration of methylated SEQ ID NO:246, lacking a phosphate backbone modification that protects against nuclease degradation *in vivo*.

In view of the lack of the predictability of the art to which the invention pertains as evidenced by Krieg, Agrawal et al and Hartmann et al, the lack of guidance and direction provided by applicant, and the absence of working examples, undue experimentation would be required to practice the claimed cancer therapy method comprising administering an immunostimulatory oligonucleotide comprising or consisting of SEQ ID NO:246 and chemotherapeutic agent, wherein the oligonucleotide lacks a backbone modification and is methylated with a reasonable expectation of success, absent a specific and detailed description in applicant's specification of how to effectively practice the claimed immunostimulatory oligonucleotide and chemotherapeutic agent and absent working examples providing evidence which is

reasonably predictive that the claimed immunostimulatory oligonucleotide and chemotherapeutic agent effectively treat cancer, commensurate in scope with the claimed invention.

10. Claims 121-138 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The response filed 6/15/2006 has introduced NEW MATTER into the claims. Newly added claims 121-138 are drawn to a method of treating cancer in a subject comprising administering an immunostimulatory oligonucleotide comprising or consisting of SEQ ID NO:246 and one or more of carboplatin, paclitaxel (taxol), cisplatin, 5-fluorouracil, doxorubicin and gemcitabine in an effective amount to treat the cancer and wherein the oligonucleotide is up to 100 nucleotides in length, is 24-40 nucleotides in length, comprises various backbone modifications and wherein the subject is human and the cancer is non-small cell lung cancer. Thus, the newly added claims are drawn to a method of treating cancer comprising administering a sub-genus of immunostimulatory oligonucleotides of various lengths and having different chemical structures or sequences, which were not clearly disclosed in the as filed application. At pg. 4 of the response, applicant points to specific page and line numbers of the as filed disclosure for support of each claim. While the specification discloses numerous

immunostimulatory oligonucleotides including the immunostimulatory oligonucleotide of SEQ ID NO:246 as well as the use of an anti-cancer therapy, inclusive to carboplatin, paclitaxel, cisplatin, 5-fluorouracil, doxorubicin and gemcitabine in combination with the immunostimulatory oligonucleotide, this does not provide adequate written support for the claimed limitations as they are currently recited. The general disclosure of immunostimulatory olignucleotides in combination with an anti-cancer therapy selected from a chemotherapeutic agent, an immunotherapeutic agent and a cancer vaccine do not provide sufficient guidance or direction to the features currently claimed. For example, there is insufficient direction and guidance for the selection of the immunostimulatory oligonucleotide of SEQ ID NO:246 from any of the other disclosed immunostimulatory oligonucleotides and in combination with one or more of carboplatin, paclitaxel (taxol), cisplatin, 5-fluorouracil, doxorubicin and gemcitabine from any of the other disclosed chemotherapeutic agents, immunotherapeutic agents and cancer vaccines. In re Ruschig, 379 F.2d 990, 154 USPQ 118 (CCPA 1967) makes clear, one cannot disclose a forest in the original application, and then later pick a tree out of the forest and say here is my invention. In order to satisfy the written description requirement, the blaze marks directing the skilled artisan to that tree must be in the originally filed disclosure. See id. at 994-95, 154 USPQ at 122; Fujikawa, 93 F.3d at 1570-71, 39 USPQ2d at 1905; Martin v. Mayer, 823 F.2d 500, 505, 3 USPQ2d 1333, 1337(Fed. Cir. 1987). As discussed above the present application lacks blaze marks leading to the presently claimed combination of SEQ ID NO:246 and one or more of carboplatin, paclitaxel (taxol), cisplatin, 5-fluorouracil, doxorubicin and gemcitabine,

sufficient to satisfy the written description requirement of the first paragraph under 35 U.S.C. 112. Further, there is insufficient written description for the subgenus of immunostimulatory oligonucleotides "comprising" up to 100 nucleotides or "comprising" 24-40 nucleotides as the as filed disclosure contains no description of the sequences contained therein and based on the disclosure of SEQ ID NO:246, one of skill in the art would reasonably conclude that the disclosure does not provide a representative number of species to describe the sub-genus. Additionally, the as filed specification only discloses SEQ ID NO:246 as having a phosphorothioate modification and the specification is devoid of examples of the claimed combination of SEQ ID NO:246 and one or more of carboplatin, paclitaxel, cisplatin, 5-fluorouracil, doxorubicin and gemcitabine, that would have led the skilled artisan to the particular combinations of the present claims. Applicants reliance on a general disclosure and possibly a single species (i.e., phosphorothioate immunostimulatory oligonucleotide SEQ ID NO:246) has not provided sufficient direction and guidance to the features currently claimed. It cannot be said that a subgenus is necessarily described by a genus encompassing it and a species upon which it reads. See In re Smith 173 USPQ 679, 683 (CCPA 1972) and MPEP 2163.05. The newly presented claims now recite limitations, which were not clearly disclosed in the specification as filed, and now change the scope of the instant disclosure as filed. Such limitations recited in the newly added claims, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C 112. Applicant is required to provide sufficient written support for the limitations recited in the present claims in the

specification or claims, as filed, or remove these limitations from the claims in response to this Office Action.

11. Claims 121-130 are rejected under 35 U.S.C. 102(e) as being anticipated by Wagner et al (US 2004/0235778 A1, 5/14/1998).

The claims are drawn to a method of treating cancer in a subject comprising administering an immunostimulatory oligonucleotide comprising or consisting of SEQ ID NO:246 and one or more of carboplatin, paclitaxel, cisplatin, 5-fluorouracil, doxorubicin and gemcitabine in an effective amount to treat the cancer and wherein the oligonucleotide is up to 100 nucleotides in length, is 24-40 nucleotides in length, comprises various backbone modifications and wherein the subject is human and the cancer is non-small cell lung cancer.

Wagner et al teach a method of treating cancer including non-small cell lung cancer in a human subject having thrombocytopenia (i.e., myelosuppression) comprising administering by injection the immunostimulatory oligonucleotide of SEQ ID NO:80, which is identical to the immunostimulatory oligonucleotide of SEQ ID NO:246 and 5-fluorouracil and wherein the immunostimulatory oligonucleotide of SEQ ID NO:80 comprises a phosphate backbone modification including a phosphorothioate modification and the backbone modification may be complete (i.e., entirely modified) (see entire document, particularly paragraphs 0073, 0080, 0134, 0153, 0164, pp. 14-18, Figs 9-13 and SEQ ID NO:80).

Thus, Wagner et al anticipate the claims.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 121-138 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wagner et al (US 2004/0235778 A1, 5/14/1998) in view of Maxwell et al (Seminars in Oncology Nursing, 8(2):113-123, May 1992).

The claims are drawn to a method of treating cancer in a subject comprising administering an immunostimulatory oligonucleotide comprising or consisting of SEQ ID NO:246 and one or more of carboplatin, paclitaxel, cisplatin, 5-fluorouracil, doxorubicin and/or gemcitabine in an effective amount to treat the cancer and wherein the oligonucleotide is up to 100 nucleotides in length, is 24-40 nucleotides in length, comprises various backbone modifications and wherein the subject is human and the cancer is non-small cell lung cancer.

Maxwell et al teach that chemotherapy-induced myelosuppression is the most common dose limiting and potentially fatal complication of cancer treatment and myelosuppression, characterized by neutropenia and thrombocytopenia are common with chemotherapy treatments and decreases the body's immune barriers and Maxwell teach the chemotherapeutic agents carboplatin, paclitaxol (taxol), cisplatin, 5-fluorouracil and doxorubicin as well as others (see entire document, particularly pp. 113, 115, 118 and Table 3). Maxwell et al do not specifically teach a method of treating cancer or non-small cell lung cancer in a human patient comprising administering the immunostimulatory oligonucleotide of SEQ ID NO:246 by injection and one or more of carboplatin, paclitaxel, cisplatin, 5-fluorouracil, doxorubicin and/or gemcitabine and wherein the olignucleotide comprises a at least one phosphate backbone modification or is entirely modified or is a phosphorothioate modification. These deficiencies are made up for in the teachings of Wagner et al.

Wagner et al have been described supra. Wagner et al also teach that the administration of CpG oligonucleotides induces hematopoiesis of specific immune cells

such as platelets and erythroblasts in patients suffering from myelosuppression or thrombocytopenia as a consequence of chemotherapeutic induced thrombocytopenia (see pp. 16-18).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to have produced a method for treating cancer or non-small cell lung cancer in a human patient comprising administering by injection the immunostimulatory oligonucleotide of SEQ ID NO:80 in combination with one or more of carboplatin, paclitaxel, cisplatin, 5-fluorouracil and/or doxorubicin in an effective amount to treat the cancer.

One of ordinary skill in the art would have been motivated to and had a reasonable expectation of success to have produced a method for treating cancer or non-small cell lung cancer in a human patient comprising administering by injection the immunostimulatory oligonucleotide of SEQ ID NO:80 in combination with one or more of carboplatin, paclitaxel, cisplatin, 5-fluorouracil and/or doxorubicin in an effective amount to treat the cancer in view of Maxwell et al and Wagner et al because Maxwell et al teach that chemotherapy-induced myelosuppression is the most common dose limiting and potentially fatal complication of cancer treatment and myelosuppression, characterized by neutropenia and thrombocytopenia are common with chemotherapy treatments and decrease the body's immune barriers and Maxwell teach the chemotherapeutic agents carboplatin, paclitaxol (taxol), cisplatin, 5-fluorouracil and doxorubicin, among others, and Wagner et al teach a method of treating cancer including non-small cell lung cancer in a human subject having thrombocytopenia (i.e.,

myelosuppression) as a consequence of chemotherapy comprising administering by injection the immunostimulatory oligonucleotide of SEQ ID NO:80 (identical to the immunostimulatory oligonucleotide of SEQ ID NO:246) for inducing hematopoiesis of specific immune cells such as platelets and erythroblasts. Therefore, one of ordinary skill in the art would have been motivated by the goal of reducing chemotherapy-induced myelosuppression in cancer patients, to administer by injection the immunostimulatory oligonucleotide of SEQ ID NO:80 in combination with one ore more of carboplatin, paclitaxol (taxol), cisplatin, 5-fluorouracil and/or doxorubicin, in order to induce hematopoiesis of immune cells such as platelets and erythroblasts, thereby countering the dose-limiting toxicities associated with chemotherapy in cancer patients. Further, one of ordinary skill in the art would have had a reasonable expectation of success in making the above modification in view of the teachings of Wagner et al, providing evidence that the combination of a chemotherapeutic agent and an immunostimulatory oligonucleotide reduces the loss of platelets compared to chemotherapeutic agent alone (see Fig. 13). Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have produced a method for treating cancer or non-small cell lung cancer in a human patient comprising administering by injection the immunostimulatory oligonucleotide of SEQ ID NO:80 in combination with one or more of carboplatin, paclitaxel, cisplatin, 5-fluorouracil and/or doxorubicin in an effective amount to treat the cancer in view of Maxwell et al and Wagner et al.

Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Conclusion

14. No claim is allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Blanchard whose telephone number is (571) 272-0827. The examiner can normally be reached at Monday through Friday from 8:00 AM to 6:00 PM, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832. The official fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,
David J. Blanchard
571-272-0827